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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,543	03/01/2004	Thomas Cavanak	100-6403R	9687

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 04/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/790,543	CAVANAK ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-7,10-16 and 18-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,27 and 29-37* is/are rejected.

7)☒ Claim(s) *3,5-7,10-16,18-26,28 and 38-48* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 07/481,082.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The amendment to the second paragraph on page 11 contained in the response filed February 28, 2005 is in improper format under 37 CFR 1.121(b)(1)(ii) because "parameters" was inserted into the claim without underlining. The amendment to the third complete paragraph on page 19 is in improper format under 37 CFR 1.121(b)(1)(ii) because "polyol" was inserted into the claim without underlining. The amendment to claim 30 is in improper format under 37 CFR 1.121(c) because "dioctylsuccinate" was changed to "dicotylsuccinate" without showing the change with strikethrough and underlining as required by 37 CFR 1.121(c)(2).

2. Claim 30 is objected to because of the following informalities: At claim 30, line 4, "dioctylsuccinate" is misspelled. Appropriate correction is required.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,262,022. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '022 patent anticipate the instant claims. Note that an intended use limitation does not impart patentability to product claims where the product is otherwise taught by the reference.

In any event, the capsule form recited in claim 12 of the '022 patent is a form suitable for oral administration.

5. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-64 of U.S. Patent No. 5,916,589. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '589 patent anticipate the instant claim. Note that the '589 patent claims cyclosporin-containing compositions which comprise a fatty acid triglyceride (see, e.g., claims 8 and 20) and a glycerol fatty acid partial ester, i.e. a monoglyceride such as glycerol monooleate (see, e.g., claims 10 and 22).

6. Claim 2 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,652,212. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '212 patent anticipate the instant claim.

7. Claims 1, 27, and 29-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 5,639,724. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '724 patent anticipate instant claims 1, 27, 30, 32, 33, 35, and 36. With respect to instant claims 29, 31, 34, and 37, while the '724 patent does not claim the concentrations and proportions recited in the instant claims, it would have been obvious to one of ordinary skill in the art to determine all operable and optimal concentrations and proportions for the claimed compositions of the '724 patent because concentration and proportion are art-

recognized result-effective variables which are routinely determined and optimized in the pharmaceutical composition arts.

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,916,589. The '589 patent teaches, in Examples 1.6 - 1.8, cyclosporin-containing compositions comprising Miglyol 812 (which comprises fatty acid triglycerides) and glycerol monooleate (which is a glycerol fatty acid partial ester).

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Cavanak (U.S. Patent No. 4,388,307). Cavanak teaches cyclosporin-containing compositions comprising saturated fatty acid triglycerides and mono- or di-glycerides of fatty acids (i.e., glycerol fatty acid partial esters). See, e.g., the Abstract and column 4, lines 3-39.

11. Claims 1, 27, 29, 30, and 32-37 are rejected under 35 U.S.C. 102(b) as being anticipated by the Belgian Patent '724 in view of Applicants' admission of the prior art at page 9, lines 26-30; page 15, lines 17-32; and page 19, lines 16-18 and 21-22, of the specification. The Belgian Patent '724 teaches cyclosporin compositions comprising Dihydrocyclosporin D (which corresponds to the second member of the Markush group in Applicants' claim 5) and a carrier medium comprising ethanol, "MAISINE7", and optionally "CREMOPHOR7 RH 40" (an emulsifying agent formed by reacting hydrogenated castor oil with ethylene oxide) or "IMWITOR7 742" or "LABRAFIL7 2125" (a polyoxyethylated kernel oil). The compositions are to be administered orally in unit dosage form, optionally in combination with a chocolate flavour-masking component. See Examples 1 and 2. Example 2 is substantially free of ethanol.

Applicants admit at page 9, lines 26-30, and page 15, lines 17-32, of the specification that "MAISINE7" is the tradename of a trans-esterification product of corn oil with glycerol, comprising triglycerides, diglycerides, monoglycerides, and free glycerol in the ratios claimed by Applicants. Applicants admit at page 19, lines 16-18, of the specification that "LABRAFIL7" is a trans-esterification product of a natural vegetable oil and a polyalkylene polyol. Applicants admit at page 19, lines 21-22, of the specification that "IMWITOR7" is an esterification product of caprylic and caproic acid.

12. Claim 31 is rejected under 35 U.S.C. 103(a) as being obvious over the Belgian Patent '724 in view of Applicants' admission of the prior art at page 9, lines 26-30; page 15, lines 17-32; and page 19, lines 16-18 and 21-22, of the specification. Application of the Belgian Patent '724 and Applicant's admission is the same as in the above rejection of claims 1, 27, 29, 30, and 32-37. In Example 1 of the Belgian Patent '724, the ratio of Dihydrocyclosporin D to "CREMOPHOR7 RH 40" is not 1:at least 1. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimum proportions of Dihydrocyclosporin D and "CREMOPHOR7 RH 40" for use in the invention of the Belgian Patent '724 because the disclosure of the Belgian Patent '724 is not limited to any particular proportions of components in its pharmaceutical compositions and because it is routine in the art to determine all operable and optimal proportions of components in pharmaceutical compositions.

13. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by the Chemical Abstract 92:64765k. The Chemical Abstract 92:64765k teaches a pharmaceutical composition

comprising Cyclosporin A, an ester of a triglyceride with a polyalkylene glycol, e.g., "LABRAFIL M 1944", a fatty acid triglyceride, and a mono- or di-glyceride.

14. Applicant's arguments filed February 28, 2005 have been fully considered but they are not persuasive.

The obviousness-type double patenting rejection of claim 1 over U.S. Patent No. 5,916,589 is maintained. Except for a rote recitation of the instant claimed subject matter and the subject matter claimed in the '589 patent and a conclusion that the latter does not suggest the former, Applicants' arguments do not particularly point out what part of the instant claimed subject matter is not suggested by the claims of the '589 patent. There is no discussion in the arguments of claims 8 and 20 (drawn to a fatty acid triglyceride component) and claims 10 and 22 (drawn to a glycerol fatty acid partial ester component) of the '589 patent, specifically discussed in the rejection.

The anticipation rejection of claim 1 over U.S. Patent No. 5,916,589 is maintained. Applicants point to some additional ingredients which are present in the examples of the '589 patent and which are not recited in instant claim 1. Presumably, Applicants are arguing that the "consisting essentially of" language which has been inserted into instant claim 1 excludes the presence of these additional components from Applicants' claimed compositions. However, "consisting essentially of" language excludes only those components which materially affect the basic and novel characteristics of Applicants' claimed compositions, with the burden being upon Applicants to make this showing. See MPEP 2111.03. No such showing has been made by Applicants. Further, because the intended uses of the '589 patent's compositions are the same as for Applicants' claimed compositions, i.e. orally administered immunosuppressants, it is not

clear that the additional components which are present in the compositions of the '589 patent have any effect on the basic and novel characteristics of Applicants' invention. Finally, because Applicants' dependent claims 30 and 36 explicitly recite that the reaction product of a natural or hydrogenated castor oil and ethylene oxide and that a glycerol fatty acid partial ester can be present in the claimed compositions, the examiner does not understand upon what basis it can be argued that independent claim 1 does not permit the presence of such components.

The anticipation rejection of claim 1 over Cavanak (U.S. Patent No. 4,388,307) is maintained. Applicants point to page 10 of the present specification as showing that "the carrier systems of the present invention are oil-based compositions, which are not aqueous emulsions and which do not require the presence of additional solvents, co-solvents or solubilizers". However, Applicants' citation is to the specification and not to any limitations present in instant claim 1. Patentability must be based upon claimed, not unclaimed, differences over the prior art.

The anticipation rejection of claim 1 and certain of its dependent claims over the Belgian Patent '724 in view of Applicants' admission of the prior art at page 9, lines 26-30; page 15, lines 17-32; and page 19, lines 16-18 and 21-22, of the specification is maintained. Again, Applicants merely list the ingredients which are present in the prior art compositions and which are recited in the instant claims, and do not provide any evidence or arguments which would satisfy Applicants' burden of showing that any additional components which are present in the prior art compositions are excluded by the "consisting essentially of" language.

The obviousness rejection of claim 31 over the Belgian Patent '724 in view of Applicants' admission of the prior art at page 9, lines 26-30; page 15, lines 17-32; and page 19, lines 16-18

and 21-22, of the specification is maintained. The rejected claim does not require that the composition be free or substantially free of ethanol.

Claim 2 and the claims dependent upon it. and claim 28, are no longer rejected over the Belgian Patent '724 because these claims have been amended to require a transesterification product of a hydrogenated (as opposed to a natural) vegetable oil with glycerol or propylene glycol. The examiner can find no evidence which shows that the Maisine7 of the Belgian Patent '724 is formed from a hydrogenated corn oil.

The anticipation rejection of claim 1 over the Chemical Abstract 92:64765k is maintained. Again, Applicants merely list the prior art and claimed components and do not explain why the compositions of the Chemical Abstract do not anticipate Applicants' claimed compositions.

15. Claims 3, 5-7, 10-16, 18-26, 28, and 38-48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

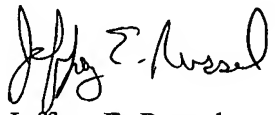
16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

April 5, 2005